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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,879	11/21/2001	Alan Engelman	700157/50007-C	2216

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EXAMINER

GUZO, DAVID

ART UNIT	PAPER NUMBER
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1636

14

DATE MAILED: 09/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/990,879

Applicant(s)

ENGELMAN ET AL.

Examiner

David Guzo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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### Detailed Action

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 7-10, 12, 14-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Gottlinger et al.

Applicants claim a retroviral vector system comprising at least three vectors comprising sequences encoding lentiviral gag, env and pol proteins wherein the integrase (encoded by the pol gene) is modified so as to render it incapable of mediating integration of the viral nucleic acid into the host genomic DNA. The vector system also comprises a packaging vector comprising a heterologous gene encoding a protein of interest (i.e. a target protein) operably linked to a promoter (i.e. an inducible promoter), a packaging sequence, and an origin of replication (ori) and a protein that acts as a replication transactivator.

Gottlinger et al. (U.S. Patent 6,479,281, issued 11/12/02, priority to 4/2/98, see whole document, particularly column 5, lines 54-65; column 7, lines 45-67; column 8, lines 52-67; column 9, lines 1-14; column 9, lines 48-67; column 10 and 11; column 16, lines 11-17 and column 22, lines 17-24) recites a retroviral vector system comprising at least three vectors wherein the lentiviral (which can be any primate lentivirus such as

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HIV) gag and pol genes can be on the same vector or different vectors, the env (which can be a non-retroviral env) gene can be on a separate vector (the gag, pol and env vectors do not have packaging sequences) and a packaging vector. The gag, pol and env genes are under control of a promoter and polyA sequence and the integrase can be mutated so as to render it inactive (Asp116 Ala mutation). The packaging vector has a packaging sequence and the components of a replicon (i.e. a DNA ori and viral protein(s) which transactivate replication from the ori). The heterologous nucleic acid in the packaging vector can be operably linked to an inducible promoter and can encode a therapeutic gene, receptors, or an antisense molecule, etc. With regard to claim 15, the limitation of the packaging vector comprising a nucleic acid encoding a target molecule "selected from a plurality of target molecules" carries no patentable weight here because this limitation adds nothing to the claimed composition. The composition comprises a viral vector system with the recited components; the source from which the components were selected adds nothing to the final composition comprising a packaging vector containing a heterologous sequence of interest. Gottlinger et al. therefore teaches the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 1 (and dependent claims) are vague in that applicants recite a packaging vector containing “at least **one component** (emphasis added) of an episomal replicon” wherein the replicon comprises a viral DNA origin of replication and a protein that acts as a transactivator. If the vector only has one component of the replicon (i.e. only a protein that acts as a replication transactivator without a DNA ori) it is unclear how the vector can function as an episome.

Claim 15 is vague in the recitation of a packaging vector comprising a nucleic acid operably linked to a “component of an episomal replicon”. It is unclear if applicants are reciting a functional episomal replicon here. Merely reciting a “component” of the episomal replicon does not indicate whether the episomal replicon is functional or not, for example, a nucleic acid operably linked to a viral DNA ori requiring the presence of a transactivating protein would be inoperative without the transactivating protein.

### Miscellaneous

The specification contains numerous typographical errors that must be corrected. For example, on page 1, line 2, targeted is misspelled as “targetted”; on page 2, line 7, focused is misspelled as “focussed”; on page 2, line 13, multivalent is misspelled as “multivaliant”, etc. Applicants are encouraged to carefully review the specification and correct all typographical errors.

In Claim 5, the word transactivates is misspelled as “transactivatoer”. Correction is required.

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No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (703) 308-1906. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David Guzo  
September 27, 2003

  
DAVID GUZO  
PRIMARY EXAMINER